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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,164	08/30/2006	Naoki Nagahara	2006_1328A	6045

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WENDEROTH, LIND & PONACK, L.L.P.
1030 15th Street, N.W.,
Suite 400 East
Washington, DC 20005-1503

EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/18/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
eoa@wenderoth.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,164	NAGAHARA ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,12-14 and 18-24* is/are pending in the application.

4a) Of the above claim(s) *3,6 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-5, 12, 14, and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/4/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/4/2011 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 4-5, 12, 14, and 18-24 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) in view of US 6887307 ('307) is maintained.

Applicant argues that pullulan capsules are not generally used because the pullulan capsule was developed only recently. When a capsule other than gelatin is used, those skilled in the art will naturally selected HPMC capsules because they are known to be safe and useful. Further, the amended claims are to at least two solid preparations having different medicine release properties, which is not taught or suggested by '052 or '307.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner has established the reason one would choose pullulan capsules. The rationale for using the pullulan capsules of '307 is that they exhibit low oxygen permeability, lower water content, and high stability. That they are relatively new in the area of capsule manufacturing is not a reason for the ordinary artisan to not select them. '307 is prior art against the instant application, and '307 teaches that pullulan offer advantages over gelatin capsules, specifically they exhibit low oxygen permeability, lower water content, and high stability, and it would have been obvious to use pullulan capsules in place of the gelatin capsules of '052 for the reasons of record. Regarding the limitation in claim 1 requiring at least two solid preparations, the only distinguishing characteristic between the "at least two solid preparations" is that they have "different medicine release properties". In a given granule formulation where microtablets are coated with an enteric coating, such as the microtablets made in Example 1 of '052, each particle in the formulation will have a slightly different radius and a slightly different amount of enteric coating. The particles in '052 are made by milling, and in this method of making each particle will have a slightly different radius, and upon coating, each

particle will have a slightly different amount of enteric coating. The slight difference in radius and amount of enteric coating will give rise to a slightly different release profile from particle to particle. This difference will be small, but there will be a difference. As the only distinguishing characteristic between the "at least two solid preparations" in claim 1 is that they have "different medicine release properties", the Examiner submits that the enteric coated particles of '052, although made in a single batch, meet this requirement, because all of the particles provide a slightly different release profile. For the sake of argument, even if all the particles in the preparation of '052 have identical release profiles, this limitation in claim 1 still does not distinguish Applicant's invention over '052, because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It would have been obvious to add two separately made particle formulations of '052 to a single capsule, to produce a third composition useful for the same purpose, i.e. treatment of gastrointestinal diseases ('052: paragraph 64). For example, it would have been obvious to prepare one particle preparation with a particular enteric polymer (such as cross-linked polyvinyl pyrrolidione, taken from paragraph 19 of '052), another particle preparation with a different enteric polymer (such as hydroxypropylmethyl cellulose phthalate, taken from paragraph 19 of '052), and add the two particle preparations to a single capsule, to create a formulation for treating gastrointestinal diseases. Preparing single formulations that are made up of different release profiles of the same drug is a common tool in the art to provide varied

release of the drug. In the instant case, the expectation of success is high, as '052 teaches that a combination of enteric coatings may be used (paragraph 19).

New Grounds of Rejection

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 12, 14, and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the limitation "granules in combination" means. This is not a term of art and is not defined by the specification. The specification states at page 6, lines 11-14 "...which contains at least two solid preparations selected from fine granules, granules and tablets in combination". However there is no definition of what "granules in combination" means. What are the granules in combination with? Are the granules in combination with themselves? Are they linked together in some way?

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAUL DICKINSON/
Examiner, Art Unit 1618

May 14, 2011